JUN 1 9 2003

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510(k) SUMMARY

for the Inion OTPS™ Biodegradable Fixation System

MANUFACTURER

Inion Ltd.
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Contact Person:
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DEVICE NAME

Trade name: Inion OTPS™ Biodegradable Fixation System
Classification Name: bone, fixation, screw

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification panel: Orthopedic
Regulatory Class: Class II
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener, 87-HWC

PREDICATE DEVICES

(1) Bionx Inc.; SmartScrew (K012001, K003077)
(2) Biomet Bone Screw (K964970)

Date:20.3.2003
Status: Final

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Biodegradable Fixation System is generally intended for maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.

The Inion OTPS™ Biodegradable Fixation System is made of resorbable polylactic acid / trimethylenecarbonate copolymers [Poly (L-lactide-co-D,L-lactide) and poly (L-lactide-co-trimethylenecarbonate)]. The Inion OTPS™ Biodegradable Fixation System implants gradually lose their strength during 18-36 weeks in vivo with complete strength loss and resorption within two to four years.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion OTPS™ Biodegradable Fixation System is substantially equivalent to biodegradable implants, intended for similar indications, which have received 510(k) clearance. Inion OTPS™ Biodegradable Fixation System implants, Bionx Inc. SmartScrew (K012001, K003077) and Biomet Bone Screw (K964970) have the same intended use and principles of operation and very similar design characteristics. Mechanical testing demonstrates that the device is substantially equivalent to the predicate ones. Differences between the Inion OTPS™ Biodegradable Fixation System and predicate devices do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2003

Ms. Hanna Marttila
Regulatory Affairs Manager
Inion Ltd.
Lääkärinkatu 2
Fin-33520 Tampere
Finland

Re: K030900
Trade/Device Name: Inion OTPS™ Biodegradable Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 19, 2003
Received: March 24, 2003

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.
510(k) Number: K030900
Device Name: Inion OTPS™ Biodegradable Fixation System

Indications:

The Inion OTPS Biodegradable Fixation System is generally intended for maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.

Specific indications:

- Fractures and osteotomies of the malleoli
- Ankle fractures

Contraindications:

The OTPS Biodegradable Fixation System is not intended for use in and is contraindicated for:
1. Active or potential infection
2. Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed. (e.g., alcoholism, drug abuse)
3. High load bearing applications

Prescription use ___Yes___ Over the Counter use ___No___

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030900

Date: 19.3.2003
Status: Final